

CLAIMS

1. An oral drug delivery system which comprises a biliquid
foam comprising:
5 from 1 to 20% by weight of a continuous
hydrophilic phase,
from 70 to 98% by weight of a pharmaceutically
acceptable oil which forms a discontinuous phase, the
said pharmaceutically acceptable oil having dissolved
10 or dispersed therein a poorly water-soluble drug in an
amount of from 0.1 to 20% by weight
and the biliquid foam including therein from 0.5 to 10% by
weight of a surfactant to enable the formation of a stable
biliquid foam, all percentages being based upon the total
15 weight of the formulation.
2. An oral drug delivery system as claimed in claim 1
wherein the continuous hydrophilic phase is an aqueous
phase.
20
3. An oral drug delivery system as claimed in claim 2
wherein the aqueous phase is water.
4. An oral drug delivery system as claimed in claim 2
25 wherein the aqueous phase incorporates a salt or a co-
solvent therein.
5. An oral drug delivery system as claimed in claim 1
wherein the continuous hydrophilic phase is a non-aqueous
30 solvent.

6. An oral drug delivery system as claimed in claim 5 wherein the non-aqueous solvent is an aliphatic alcohol, polyethylene glycol, propylene glycol or glycerol, or mixtures thereof.

5

7. An oral drug delivery system as claimed in any one of the preceding claims wherein the pharmaceutically acceptable oil is a mono-, di- or triglyceride, or a mixture thereof.

10 8. An oral drug delivery system as claimed in claim 7 wherein the mono-, di- or triglycerides are the glycerol esters of fatty acids containing from 6 to 22 carbon atoms.

15 9. An oral drug delivery system as claimed in any one of the preceding claims wherein the surfactant comprises an alkyl polyglycol ether, an alkyl polyglycol ester, an ethoxylated alcohol, a polyoxyethylene sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a polyoxyethylene fatty acid ester, an ionic or non-ionic surfactant, a
20 hydrogenated castor oil/polyoxyethylene glycol adduct containing from 25 to 60 ethoxy groups, a castor oil/polyoxyethylene glycol adduct containing from 25 to 45 ethoxy groups, or mixtures thereof.

25 10. An oral drug delivery system as claimed in any one of the preceding claims which includes therein a co-emulsifier in an amount sufficient to complete the solubilization of the poorly water-soluble drug.

30 11. An oral drug delivery system as claimed in claim 10 wherein the co-emulsifier is a phosphoglyceride or a phospholipid.

12. An oral drug delivery system as claimed in any one of the preceding claims wherein the discontinuous phase comprises from 85 to 96% by weight of the biliquid foam.

5 13. An oral drug delivery system as claimed in claim 12 wherein the discontinuous phase comprises from 90 to 95% by weight of the biliquid foam.

10 14. An oral drug delivery system as claimed in any one of the preceding claims wherein the continuous hydrophilic phase comprises from 2 to 10% by weight of the biliquid foam.

15 15. An oral drug delivery system as claimed in any one of the preceding claims wherein the surfactant comprises from 0.5 to 5% by weight of the composition.

20 16. An oral drug delivery system as claimed in any one of the preceding claims wherein the poorly water-soluble drug is an analgesic or anti-inflammatory agent, an anthelmintic, an anti-arrhythmic agent, an anti-coagulant, an anti-depressant, an anti-diabetic, an anti-epileptic, an anti-fungal agent, an anti-gout agent, an anti-hypertension agent, an anti-malarial, an anti-migraine agent, an anti-muscarinic agent, an anti-neoplastic agent, an anti-
25 protozoal agent, an anti-thyroid agent, an anxiolytic, sedative, hypnotic or neuroleptic agent, a corticosteroid, a diuretic, an anti-Parkinsonian agent, a gastro-intestinal agent, a histamine H-receptor antagonist, a lipid regulating
30 agent, an anti-anginal agent, a nutritional agent, an opiod analgesic, a sex hormone, a stimulant, or a therapeutic mixture thereof.

17. An oral drug delivery system as claimed in any one of the preceding claims which is in a unit dosage form.

18. An oral drug delivery system as claimed in claim 17
5 wherein the unit dosage form comprises capsules filled with the biliquid foam.

19. An oral drug delivery system as claimed in claim 18 wherein the capsules are hard or soft gelatin capsules.

10

20. An oral drug delivery system as claimed in any one of claims 1 to 16 which is in the form of a dilutable concentrate.

15 21. An oral drug delivery system as claimed in claim 20 which is infinitely dilutable in a co-solvent.

22. An oral drug delivery system as claimed in any one of the preceding claims for use in a method of treatment by
20 oral administration to the human or animal body.